RD2009-18

Registration Decision

Roctenol, (3R)-1-octen-3-ol

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Registration Decision for Roctenol

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of technical grade active ingredient roctenol, containing (3R)-1-Octen-3-ol.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This product was first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2009-09, *Roctenol, (3R)-1-octen-3-ol*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for roctenol and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-09. This decision is consistent with the proposed registration decision stated in PRD2009-09.

For more details on the information presented in this Registration Decision, please refer to the PRD2009-09 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Roctenol?

Roctenol is the resolved isomer of the currently registered octenol (Registration Number 28439) which is a naturally occurring and ubiquitous chemical secreted by mushrooms, plants and mammals. Roctenol is a semiochemical which modifies the behaviour of some insects.

Health Considerations

Can Approved Uses of Roctenol Affect Human Health?

The technical grade active ingredient, roctenol, is chemically similar to the currently registered active ingredient, octenol, in that the overall toxicity of the optically pure form, roctenol, is expected to resemble that of the racemic mixture of octenol. According to the available information, roctenol is moderately acutely toxic when administered by the oral route, is expected to have a low acute dermal toxicity, is a mild irritant when applied to the eyes and skin, but is not a skin sensitizer. Roctenol is not expected to genotoxic, nor is it expected to be a short-term or a prenatal developmental toxicant.

Residues in Water and Food

The registration of the active ingredient, roctenol, is not for use on food or feed, thus, dietary risks from food and water are not of concern.

Occupational Risks From Handling Roctenol

Potential worker and/or bystander exposure to end-use products containing roctenol as the active ingredient was not considered because only the technical grade active ingredient was submitted for registration. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration. A risk assessment for roctenol will be conducted upon receipt of an application for the technical in an end-use product.

Environmental Considerations

What Happens When Roctenol is Introduced Into the Environment?

The PMRA expects roctenol to behave similarly to octenol in the environment, in that it is more target specific than conventional insecticides, is used at concentrations close to or lower than those occurring in nature, and dissipates rapidly. Based on octenol, roctenol is expected to be very soluble in water, indicating a potential for leaching into groundwater. The vapour pressure for roctenol is expected to be highly volatile, with the Henry's law constant indicating that it is volatile from a water surface. As well, the log K_{ow} indicates a limited potential for bioconcentration.

Semiochemicals generally dissipate rapidly in the terrestrial and aquatic environments, primarily by volatilization and degradation. Roctenol is expected to volatilize from soil and water surfaces rapidly.

For more information on the fate and behaviour of roctenol, refer to the published documents on octenol (Proposed Registration Decision Document PRDD2006-03, *Octenol* and Registration Decision Document RDD2007-01, *Octenol*.

Value Considerations

The value assessment for roctenol will be conducted upon receipt of an application for the technical in an end-use product.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Roctenol address the potential risks identified in this assessment.

Other Information

The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

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[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1081835
Reference: Appendix D: Data From Aldrich Compilation In : Boiling Point Of 1-octen-3-ol. Data Numbering Code: 2.14.5, 2.14.6 Confidential Business Information

PMRA Document Number: 1081837
Reference: Appendix F: Water Solubility Of 1-octen-3-ol, In: RIFM Monograph #492, Data Numbering Code: 2.14.11, 2.14.7 Confidential Business Information

PMRA Document Number: 1081838
Reference: N/s, Appendix G: Solubility Of 1-octen-3-ol In Organic Solvents. Fenaroli's Handbook Of Flavor Ingredients, Data Numbering Code: 2.14.8 Confidential Business Information

PMRA Document Number: 1081839
Reference: Appendix H: Estimation Of Vapor Pressure Of 1-octen-3-ol. Data Numbering Code: 2.14.9 Confidential Business Information

PMRA Document Number: 1081867
Reference: Appendix D: Data From Aldrich Compilation In : Boiling Point Of 1-octen-3-ol. Data Numbering Code: 2.14.5, 2.14.6 Confidential Business Information

PMRA Document Number: 1081869
Reference: N/s, Appendix F: Water Solubility Of 1-octen-3-ol, In: Material Information On 1-octen-3-ol. RIFM Monograph #492, Data Numbering Code: 2.14.11, 2.14.7 Confidential Business Information

PMRA Document Number: 1081870
Reference: Appendix G: Solubility Of 1-octen-3-ol In Organic Solvents. Data Numbering Code: 2.14.8 Confidential Business Information

PMRA Document Number: 1081871
Reference: Appendix H: Estimation Of Vapor Pressure Of 1-octen-3-ol. Data Numbering Code: 2.14.9 Confidential Business Information

PMRA Document Number: 1565362
Reference: 2006, Preliminary Analysis And Certified Limits, Data Numbering Code: 2.12.1, 2.12.2, 2.13.1, 2.13.2, 2.13.3, 3.3.1, 3.3.2

PMRA Document Number: 1565363
Reference: 2006, Preliminary Analysis And Certified Limits, Data Numbering Code: 2.12.1, 2.12.2, 2.13.1, 2.13.2, 2.13.3, 3.3.1, 3.3.2, Confidential Business Information

PMRA Document Number: 1652666
Reference: 2008, Specific Response To Clarification Request, Data Numbering Code: 2.11.3, 2.12.2, 2.13.1, 2.14.13, 2.14.7, 2.15

PMRA Document Number: 1652667
Reference: 2008, Specific Response To Clarification Request, Data Numbering Code: 2.11.3, 2.12.2, 2.13.1, 2.14.13, 2.14.7, 2.15 Confidential Business Information

PMRA Document Number: 1700938
Reference: 2009, Specific Response To Clarification Request, Data Numbering Code: 2.14.13

PMRA Document Number: 1711105
Reference: 2006, Enforcement Analytical Method, Data Numbering Code: 2.13.1

PMRA Document Number: 1711106
Reference: 2009, Response To Request For Clarification: Chromatograms, Data Numbering Code: 2.13.1 Confidential Business Information

2.0 Human and Animal Health

PMRA Document Number: 1061413
Reference: 2005, Waiver Request For Genotoxicity:, Data Numbering Code: 4.5.4,4.5.5,4.5.6

PMRA Document Number: 1061414
Reference: 2000, Cadby, P. The Risk Assessment Of Flavoring Agents. The Toxicology Forum-European Meeting 2000, Data Numbering Code: 4.5.4

PMRA Document Number: 1061415
Reference: 1995, Reverse Mutation Assay Ames Test Using Salmonella Typhimurium, Data Numbering Code: 4.5.4

PMRA Document Number: 1061416
Reference: 2000, International Life Sciences Institute, Threshold Of Toxicological Concern For Chemical Substances Present In The Diet, Data Numbering Code: 4.5.4

PMRA Document Number: 1061417
Reference: 2001, Micronucleaus Test In Bone Marrow Cells Of The Mouse With Linalool, Data Numbering Code: 4.5.4

PMRA Document Number: 1061418
Reference: Williams. G. World Health Organization Food Additive Series: 52. Aliphatic, Alycyclic, Linear, Alpha, Beta- Unsaturated, Di- And Trienals And Related Alcohols, Acids And Esters, Data Numbering Code: 4.5.4

PMRA Document Number: 1565365
Reference: 2005, Acute Oral Toxicity, 05-3256-g1, MRID: 46835404, Data Numbering Code: 4.2.1,4.6.1,870.1100

PMRA Document Number: 787419
Reference: Waiver Request For Genotoxicity: Microbial Point Mutation. Data Numbering Code: 4.5.4

PMRA Document Number: 787420
Reference: Waiver Request For Genotoxicity: Mammalian (cell) Point Mutation. Data Numbering Code: 4.5.5

PMRA Document Number: 787421
Reference: Waiver Request For Genotoxicity: In Vitro Chromosomal Aberrations. Data Numbering Code: 4.5.6

3.0 Environment

PMRA Document Number: 1576934
Reference: 2004. Summary of Environmental Toxicology of Bedoukian Octenol Technical
Comments: Waiver Request

B. Additional Information Considered

i) Published Information

1.0 Impact on Human and Animal Health

PMRA Document Number: 1743249
Reference: 2003, US EPA 1-octen-3-ol (067037) Fact Sheet. Data Numbering Code: 4.8

PMRA Document Number: 1743255
Reference: 2007, US EPA Octenol Fact Sheet: 1-octen-3-ol (069037) & R-(-)-1-octen-3-ol (069038) Fact Sheet. Data Numbering Code: 4.8

PMRA Document Number: 1743283
Reference: 2009, Chemical Properties Of Attractants - Catching Tsetse. Data Numbering Code: 4.8

PMRA Document Number: 1743328
Reference: 2009, World Health Organization Food Additives Series: 50, Annex 4, Acceptable Daily Intakes, Other Toxicological Information, And Information On Specifications, Jecfa Food Additives Series 50. Data Numbering Code: 4.8

PMRA Document Number: 1743259
Reference: Borg-Karlson, A.K. And I. Groth,, 1985, Volatiles From The Flowers Of Four Species In The Sections Arachnitiformes And Araneiferae Of The Genus Ophrys As Insect Mimetic Attractants, *Phytochemistry*, Vol. 25, No. 6, pp. 1297-1299, 1986, Data Numbering Code: 4.8

PMRA Document Number: 1743266
Reference: Hall, D.R. Beevor, P.S. Cork, A. Nesbitt, B.F. And G.A. Vale, 1983, 1-octen-3-ol - A Potent Olfactory Stimulant And Attractant For Tsetse Isolated From Cattle Odours, *Insect Science Application*, Vol. 5, No. 5. pp 335-339, 1984, Data Numbering Code: 4.8

PMRA Document Number: 1743277
Reference: Kawasaki, W. Matsui, K. Akakabe, Y. Itai, N. And T. Kajwara, 1997, Volatiles From Zostera Marina, *Phytochemistry*, Vol. 47, No. 1, pp. 27-29, 1998, Data Numbering Code: 4.8
PMRA Document Number: 1743357

Reference: Sipes, I.G. Renwick, A.G. World Health Organization Food Additives Series: 50, Aliphatic Secondary Alcohols, Ketones And Related Esters, Jecfa Food Additives Series 50. Data Numbering Code: 4.8

PMRA Document Number: 1743324
Reference: Stumpe, M. Bode, J. Gobel, C. Wichard, T. Schaaf, A. Frank, W. Frank, M. Reski, R. Pohnert, G. And I. Feussner, 2006, Biosynthesis Of C9-aldehydes In The Moss Physcomitrella Patens, *Biochimica Et Biophysica Acta* 1761 (2006) 301-312, Data Numbering Code: 4.8

PMRA Document Number: 1743322
Reference: Walinder, R. Erstgard, L. Norback, D. Wieslander, G. And G. Johanson, 2008, Acute Effects Of 1-octen-3-ol, A Microbial Volatile Organic Compound (mvoc)-an Experimental Study, *Toxicology Letters* 181 (2008) 141-147, Data Numbering Code: 4.8

PMRA Document Number: 1743270
Reference: Zawirska-wojtasiak, R. 2003, Optical Purity Of (r)-(-)-1-octen-3-ol In The Aroma Of Various Species Of Edible Mushrooms, *Food Chemistry*, 86 (2004) 113-118, Data Numbering Code: 4.8